

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PC-8993	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2004/001928	International filing date (day/month/year) 19.02.2004	Priority date (day/month/year) 20.02.2003
International Patent Classification (IPC) or national classification and IPC A61K 9/48, A61J 3/07, A61K 47/10, 47/26, 47/34		
Applicant FREUND CORPORATION		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.	
2.	This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.	
3.	This report is also accompanied by ANNEXES, comprising: a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>2</u> sheets, as follows: <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).	
4.	This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application	

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/001928

Box No. I

Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 2, 3 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1, 4 _____ received by this Authority on 14-09-2004
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/001928

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims <u>1-4</u>	YES
	Claims _____	NO
Inventive step (IS)	Claims _____	YES
	Claims <u>1-4</u>	NO
Industrial applicability (IA)	Claims <u>1-4</u>	YES
	Claims _____	NO

2. Citations and explanations (Rule 70.7)

Documents cited in the international search report:

Document 1: JP 2001-89362 A

Document 2: JP 10-310519 A

Documents 3 to 5 below were added in response to the constituent features added by the amendment.

Document 3: JP 9-155183 A

Document 4: JP 6-134292 A

Document 5: JP 4-322741 A

Claims 1 to 4

Documents 1 to 5

Document 1 sets forth an encapsulated granular substance comprising an ingredient (filler) and a coating covering the filler, wherein crystals of the crystalline water-soluble substance (crystallizing agent) are precipitated to the external surface of the coating. Mannitol, xylitol, and other sugar alcohols are given as examples of the crystallizing agent, and seamless capsules are given as an example of the encapsulated granular substance (claims 1 to 3; paragraphs [0013], [0014] and [0018], etc.).

Moreover, embodiment 1 sets forth a seamless capsule

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

comprising vitamin E-containing oil and a coating which encapsulates this oil, wherein the coating contains 100 parts by weight of gelatine, 30 parts by weight of glycerine (plasticizer), and from 80 to 240 parts by weight of xylitol, and white crystals of xylitol are uniformly precipitated on the external surface. It is understood that the coating of said capsule is opaque. In addition, document 1 also indicates that a known method of productions can be applied to the production of said capsules (see paragraph [0019]).

In contrast, the invention of this application specifies the mass ratios of the coating and filler, the particle size and method of production of the seamless capsule, but the aforementioned mass ratios and particle size of seamless capsules is within the range of the common general technical knowledge, and do not constitute an effective difference (if necessary, see document 3 (embodiment 1), document 4, embodiments 1 to 3), and the aforementioned method of production is understood to be a known technique in common use (document 5, paragraphs [0002] to [0005]; document 3 paragraphs [0022] to [0042], etc.).

Moreover, with regard to the seamless capsule set forth in document 1, regardless of the method of production, the produced article per se is effectively no different from the seamless capsule of this application.

In addition, in the same way as glycerin, propylene glycol and polyethylene glycol are merely known plasticizers used in soft capsules (document 2, paragraphs [0012] and [0022], etc.).